

### **REMARKS**

Claims 2 and 15 remain in the application. Claim 15 is the only claim in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Dr. Kenneth I. Kohn, during a personal interview conducted on December 6, 2006. During the interview, proposed claim language was discussed. Specifically, verification was made regarding the characterization of the presently claimed invention to include the step of administering supernatant, which contains products secreted by mesenchymal stem cells. It was agreed that the prior art requires the administration of stem cells in a culture medium. Accordingly, it was agreed that the presently cited prior art does not teach the claimed invention, as set forth in the Interview Summary of record.

As further discussed at the interview, Applicants herein submit new claim 15, which details the steps of preparing the medium, thereby defining the medium per se in combination with the step of then administering the medium, thereby improving cardiac function. Applicants also attach hereto a declaration under Rule 132 by the inventor, Dr. Hani N. Sabbah, the data therein further demonstrating the profound effect of the present invention.

More specifically, and referring to the outstanding Office Action, the previously pending independent claims were rejected under 35 U.S.C. § 102(e) or 102 (b) in view of United States Patent No. 6,387,369 to Pittenger, et al. and the IDS reference to Tomita, et al. It is undisputed that both references disclose a method of improving cardiac function by the administration of cardiomyocyte producing amount of mesenchymal stem cells. During the personal interview, the Examiner noted that medium was injected along with the mesenchymal stem cells directly to the site requiring therapy, the heart tissue, per se. As stated in the Interview Summary and agreed upon at the interview, the prior art of record is drawn to the administration of stem cells, possibly in a culture medium, but not to the administration of a supernatant per se separated from cultured stem cells. Since an anticipation

rejection requires that each and every element of a pending claim be found in the single cited prior art reference and it is undisputed that the prior art references do not disclose the characterizing step of pending independent claim 15, that being the step of administering the product consisting essentially of secretions from the mesenchymal stem cells, then it must be undisputed that the prior art failed to anticipate the presently pending independent claim 15. Hence, it is respectfully submitted that presently pending independent claim 15 is patentable over the cited prior art.

During the personal interview, an issue was raised with regard to support for the steps of presently amended independent claim 15 in the specification. The following is a recitation of independent claim 15 with citations to specific page and line numbers of support for each claim step.

15. A method of improving cardiac function by:  
isolating stem cells from harvested marrow; (page 10, lines 7-9);  
growing the stem cells without differentiation in medium; (page 10, lines 7-13);  
enriching the medium containing the stem cells; (page 10, lines 18-19);  
separating the stem cells from a supernatant, the supernatant containing products consisting essentially of secretions from the stem cells; (separation procedures such as centrifugation well known in the art); and  
administering the products consisting essentially of the secretions from the stem cells (page 9, lines 15-21).

Accordingly, it must be undisputed that there is specific support for each and every limitation claimed in presently pending claim 15. It must also be undisputed that the method of separating cells from a supernatant is well known in the art, as demonstrated in the Pittenger, et al. patent, column 6, lines 13-15. However, no prior art reference teaches the administration of products consisting essentially of secretions from the mesenchymal stem cells (the supernatant) as a therapeutic for the improvement of cardiac function.

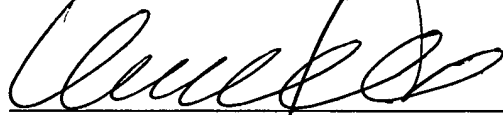
The presently pending independent claim is not a product by process claim. Rather, it is a method of improving cardiac function by specific steps set forth clearly in the claim. The Affidavit attached hereto demonstrates the repeatability of the process and the significant improved outcome by utilizing the process. In other words, the claim merely claims the process or method of improving cardiac function. If it is held that the claim is a product by process claim, then reference is made to MPEP 2173.05(b), which states that a product by process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. However, as stated above, the present claim is a method of improving cardiac function claim and not a claim to the product per se.

In conclusion, it is respectfully submitted that the present amendment place the application in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC



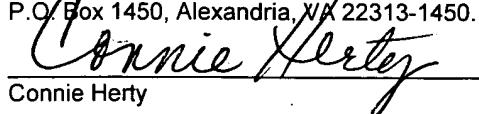
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Dated: December 15, 2006

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